DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-400/S-086

Merck & Co., Inc.
Attention: Mr. Kenneth A. Kramer
Sumneytown Pike, P.O. Box 4, BLA-20
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your electronic supplemental new drug application dated August 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aldomet™ (methyldopa) 125, 250 and 500 mg Tablets.

We acknowledge receipt of your submissions dated February 17, March 10 and April 6, 2004. Your submission of April 6, 2004 constituted a complete response to our February 27, 2004 action letter.

This supplemental new drug application provides for the establishment of a new Geriatric Use subsection under PRECAUTIONS as follows:

> Geriatric Use
> Of the total number of subjects (1685) in clinical studies of ALDOMET, 223 patients were 65 year of age and over while 33 patients were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. (See DOSAGE AND ADMINISTRATION.)
>
> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the following minor editorial revision:

> Under PRECAUTIONS, Geriatric Use, first paragraph, first sentence, the phrase “65 year of age” should be changed to “65 years of age.”

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated above, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 13-400/S-086." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge
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